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10/815,108	03/31/2004	Rakesh Tuli	U 015126-7	6584

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Ladas & Parry
26 West 61 Street
New York, NY 10023

EXAMINER

HWU, JUNE

ART UNIT	PAPER NUMBER
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1661

MAIL DATE	DELIVERY MODE
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07/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,108	Applicant(s) TULI ET AL.	
	Examiner June Hwu	Art Unit 1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☒ Claim(s) 22 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed April 10, 2007 is acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

Status of the Claims

Claims 1-25 and newly added claims 26-32 will be examined on the merits.

The objections of claims 3, 6 and 23 are withdrawn due to applicants' amendment of the claims.

The rejection of claims 1-25 under 35 USC 112, second paragraph is withdrawn due to applicant's amendment of the claims.

The rejection of claims 1, 2, 6-8, 10-18, and 19-25 under 35 U.S.C. 103(a) as being unpatentable over Mishra et al (Plant Cell, Tissue and Organ Culture 73:21-35, 2003) in view of Trolinder et al (Plant Cell, Tissue and Organ Culture 12, 43-53, 1988) is withdrawn because the claims are drawn to subculturing the embryogenic mass/clumps devoid of inositol.

The rejection of claims 3-5, and 9 under 35 U.S.C. 103(a) as being unpatentable over Mishra et al in view of Trolinder et al as applied to claims 1, 2, 6-8, 10-18 and 19-25 above, and further in view of Gupta et al (Plant Cell, Tissue and Organ Culture 51: 149-152, 1997) is withdrawn because the claims are drawn to subculturing the embryogenic mass/clumps devoid of inositol.

Claims Objection

Claim 1, line 4 is objected to because "a" should be replaced with -- the --.

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Claim 1 at part (ii) is objected to because "in" should be -- on -- at lines 6 and 7.

Claim 1, at part (vi) is objected to because "and" should be inserted after "soil".

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 is drawn to "cotton or any other plant seedlings" which is broader than claim 1 which is limited to "cotton seedling".

Claim 5, line 1 is objected to because an article is missing before "carbon" and "seed".

Claim 5, line 2 is objected to because "a" should be changed to -- the --.

Claim 6, line 18 is objected to because -- and -- should be inserted at the end of the line.

Claim 7, line 5 is objected to because -- and -- should be inserted at the end of the line.

Claim 10, line 1 is objected to because an article is missing before "gelling".

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 11 is drawn to a method of regenerating cotton seedling, wherein the first solid callus induction medium contains glucose as the primary carbon source. Claim 1 is drawn to the method of regenerating cotton seedling, wherein the first solid callus induction medium contains glucose as the primary carbon source. No limitations were recited in the claim. Thus, claim 11 fails to further limit claim 1.

Claim 15, line 1 is objected to because an article is missing before "plant".

Claim 18, line 1 is objected to because an article is missing before "potting".

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Claim 19, line 2 is objected to because an article is missing before "elite" and "transgenic".

Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 20 is drawn to "plant species other than cotton" which is broader than claim 1 which is limited to "cotton seedling".

Claim 21, line 2 is objected to because "of" should be deleted.

Claim 22, line 2 is objected to because "from" should be changed to -- form --.

Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 30 is drawn to a method of regenerating cotton wherein the explants are cultured on callus induction medium at a temperature between 23 to 33°C. Claim 12 is drawn to the method of regenerating cotton seedling, wherein the explants are cultured on callus induction medium at a temperature between 23 to 33°C. No limitations were recited in the claim. Thus, claim 30 fails to further limit claim 12.

Claim Rejections - 35 USC § 112

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

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Claim 1 at part (i), the recitation "cotyledon, hypocotyl, and mesocotyl or mixtures thereof" is unclear if applicants are referring to cotyledon and hypocotyls and mesocotyl, or cotyledon or hypocotyls or mesocotyl or cotyledon and hypocotyl or mesocotyl and cotyledon and hypocotyl. The claim is not in proper Markush format.

Claim 1 at part (i), recites the limitation "the explant" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (iii), recites the limitation "the first solid callus induction medium" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (iii), recites the limitation "the suspension" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (iv), recites the limitation "the cell suspension" in line 16. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (iv), recites the limitation "the embryogenic callus" in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (v), recites the limitation "the embryogenic mass /clumps" in line 19. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (v), recites the limitation "said basal medium devoid of inositol" in line 20. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (vi), recites the limitation "bipolar somatic embryos" in line 23. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 at part (vii), recites the limitation "the plantlets" in line 26. There is insufficient antecedent basis for this limitation in the claim.

Claim 10, recites the limitation "gelling agent in said first solid callus induction medium" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "said embryogenesis induction medium" in lines 1-2.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

Claims 1, 2, 6-8, 10-17, 19-24, 28, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mishra et al (Plant Cell, Tissue and Organ Culture 73:21-35, 2003) in view of Dasgupta et al (US 2005/0235377 A1).

The claims are drawn to a method for regeneration of cotton by somatic embryogenesis by culturing the explant consisting of cotyledon, hypocotyls and mesocotyl or mixtures thereof from cotton 'Coker 312' in solid MS medium containing glucose as the carbon source with Gamborg B5 vitamins, 2,4-D, BA, and inositol at temperature of 23 to 33°C in light condition under 16 hour photoperiod for 3-5 weeks to form callus; then transferring the callus to liquid induction MS medium containing glucose, Gamborg B5 vitamins at temperature of 23 to 33°C under reduced light intensity under 16 hour photoperiod to form embryogenic clumps; screening the cell suspension through metal sieves to select embryogenic cells and/or clumps; then culturing the embryogenic mass/clumps devoid of inositol and then returning the culture to inositol containing medium to enable somatic embryos to develop; then transferring bipolar somatic embryo to a germination medium until the plantlet stage for transfer to soil; and transferring the plantlet to potting mix for acclimation to field.

Mishra et al teach a method for regeneration of cotton through somatic embryogenesis comprising surface sterilizing the seeds of 'Coker 312' and 'Maxxa' in 1.2% sodium hypochloride solution for 20 minutes, rinsed with sterile deionized water 4-5 times (p. 22, right col. last paragraph). The seeds were germinated for 7-10 days, which is between 9-10 days at temperature of $28\pm 2^{\circ}\text{C}$ under indirect lighting (p. 23, left col., lines 3-6). Indirect lighting and

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direct lighting was a combination of 40-watt cool light and 40-watt Gro-lux fluorescent lights on a 16 hour light/8 hour dark cycle (p. 23, left col., lines 6-10). The hypocotyl explants were excised from the 7-10 days seedling and cultured at a temperature of $28\pm 2^{\circ}\text{C}$ under indirect lighting (at least $90\ \mu\text{mol}/\text{m}^2/\text{s}$) with a 16 hour photoperiod for 3 to 4 weeks in a callus induction medium (p. 23, left col., 1st full paragraph) containing MS (Murashige and Skoog) salts supplemented with $100\ \text{mg}\ \text{l}^{-1}$ myo-inositol, B5 vitamins ($10\ \text{mg}\ \text{l}^{-1}$ thiamine-HCl; $1\ \text{mg}\ \text{l}^{-1}$ nicotinic acid; $1\ \text{mg}\ \text{l}^{-1}$ pyridoxine), $0.75\ \text{g}\ \text{l}^{-1}$ MgCl_2 , $30\ \text{g}\ \text{l}^{-1}$ glucose, $0.2\ \mu\text{M}$ 2,4-D (an auxin), $10.7\ \mu\text{M}$ NAA (an auxin) adjusted at pH 5.8 before adding $2.5\ \text{g}\ \text{l}^{-1}$ Phytigel (pp. 23-24).

For regeneration of the cotton, 0.5g of callus per 15-ml of medium were transferred to liquid medium containing MS salts, $100\ \text{mg}\ \text{l}^{-1}$ myo-inositol, B-5 vitamins, $0.75\ \text{g}\ \text{l}^{-1}$ MgCl_2 , $30\ \text{g}\ \text{l}^{-1}$ glucose, $1.9\ \text{g}\ \text{l}^{-1}$ KNO_3 and adjusted to pH 5.8, and then incubated on a rotary shaker at 120 rpm under indirect lighting at $28\pm 2^{\circ}\text{C}$, which is between $27\text{-}29^{\circ}\text{C}$ (p. 24, right col., lines 4-11). The liquid cultures were incubated in foil-covered 125 ml flasks. (p. 24, right col., lines 8-9) which is under reduced lighting. Embryogenic cells of different sizes were sieved through a mesh screen (p. 25, left col., lines 6-11)).

The resulting embryogenic cell clusters and somatic embryos were cultured on semi-solid MSK medium (p. 25, left col.) under indirect lighting (p. 25, right col.) at temperature of $28\pm 2^{\circ}\text{C}$ (p. 25, right col., 1st full paragraph), which is between $27\text{-}29^{\circ}\text{C}$. The embryogenic suspension cultures could be subcultured every 2 to 4 weeks (p. 25, right col. lines 6-8).

The somatic embryos at different levels of growth (globular, heart-shaped and torpedo) were cultured on Stewart's germination medium (p. 26, left col. 1st full paragraph). When the plantlets developed 4-6 leaves and sufficient roots they were potted with Pro-mix (type of soil) (p. 26, left col. 2nd paragraph).

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The callus initiation medium contained auxin and 0.5 kinetin μM (cytokinin) (p. 23 left col. bridging to right col.). Moreover, Table 1 shows that treatment 5 with 0.2 μM 2,4-D, 5.4 μM NAA and 4.6 μM kinetin had the potential of producing somatic embryos for Acala cotton.

Mishra et al do not teach that the embryogenic mass/clumps were cultured in medium deprived of inositol before returning the embryogenic clumps to inositol containing medium for further development.

Dasgupta et al teach a method of generating a transgenic plant with enhanced stress tolerance wherein one of the plant selected is cotton [0013]. Immature embryos or immature seeds of rice were placed on MSAg medium without inositol [0121] then cocultivated on CC2 medium without inositol [0123]. The scutellar calli were subcultured on selection medium without inositol [0123] and Table 3. The calli were selected by culturing the treated calli on selection medium without inositol (7-10 days interval) until the calli reached 10 mm in size and then transferred to regeneration medium containing 100 mg inositol for a week under dark light condition [0125].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of cotton regeneration through somatic embryogenesis as taught by Mishra and combine that method by depriving the embryogenic mass/clumps of inositol for 8 to 12 days as taught by Dasgupta. One of ordinary skill in the art would have been motivated to do so given that Dasgupta subculture of calli without inositol until the regeneration medium, which eventually developed into plants (Dasgupta [0128]).

With regard to the concentration of the auxin and cytokinin it would have been obvious to alter the concentration slightly for best results of callus formation. One of ordinary skill in the art would have been motivated to do so given that Mishra noted that cytokinin in the callus initiation

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medium was not critical for the induction of embryogenic callus of Maxxa hypocotyls as long as the callus formation is of good quality (p. 29, left col. 1st full paragraph).

With regard to the reduced light intensity during the callus induction, Dasgupta was silent. Dasgupta taught that the calli were incubated under dark condition [0125] for one week, which is under reduced lighting. One of ordinary skill in the art would have been motivated to do so given that reduced lighting for culturing calli because eventually the calli developed into plants. With regard to the light intensity during the callus induction, Mishra was silent. In the specification on p. 20 line 31, it is noted that white fluorescent lighting is about 90 $\mu\text{mol}/\text{m}^2/\text{s}$. Therefore, it would have been obvious to use the lighting of 40-watt cool white and 40-watt Gro-lux as taught by Mishra because the specification is silent on the wattage of the white fluorescent. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Mishra and Dasgupta because Dasgupta has shown that inositol is not necessary for plant culture. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3-5, 9, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mishra et al in view of Dasgupta et al as applied to claims 1, 2, 6-8, 10-17, 19-24, 28, and 30-32 above, and further in view of Gupta et al (Plant Cell, Tissue and Organ Culture 51: 149-152, 1997).

The claims are drawn to cotton 'Coker 312' seedling sterilized with HgCl_2 for 5-10 minutes, then scorching the seed in flame of a spirit burner for 5-10 seconds and growing the seed on half strength MS and Gamborg B5 seed germination medium under light or dark condition at temperature of 23-33°C for a period of 6-12 days and excising the explant from the

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seedling and in the callus induction medium the cytokinin is BA (6-Benzyladenine) and transferring the plants to garden soil, sand, peat moss and vermiculite.

The teachings of Mishra et al in view of Dasgupta et al are discussed above.

Mishra et al in view of Dasgupta et al do not teach the flaming of the seed and the use of BA in the induction medium.

Gupta et al teach a method of cotton regeneration comprising the cotton seeds are surface disinfected by agitation for 7 minutes in 0.1% (w/v) HgCl_2 and then rinsing three times with sterile distilled water followed by dipping in 90% ethanol and flaming (p. 149, left col. last paragraph). The seeds were germinated on half strength of MS medium containing sucrose, solidified with 0.8% (w/v) agar and adjusted to a pH of 5.8 before autoclaving (p. 149, right col.). The seedling cultures were incubated at $25\pm 2^\circ\text{C}$ with a 16 hour photoperiod under cool light fluorescent lighting ($90\ \mu\text{mol m}^{-2}\text{s}^{-1}$) (p. 149, right col.). The explants were cultured on modified MS medium with with myo-inositol, glucose and 2.2 to $44.4\ \mu\text{M}$ BA (p. 149, right col. to p. 150, left col.). The pH was 5.8 before autoclaving and medium was solidified with 0.6% of agar (p. 149, right col.). The cultures were incubated at $25\pm 2^\circ\text{C}$ with a 16 hour photoperiod by cool light fluorescent ($90\ \mu\text{mol m}^{-2}\text{s}^{-1}$) (p. 150, left col., lines 3-5). Some of the Khandwa-2 plants were grown in vermiculite and survived (p. 151, left col. 1st full paragraph). Some plants were transferred to Hoagland's solutions for about 2 weeks then were transferred to soil (p. 151, right col. lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of cotton regeneration through somatic embryogenesis as taught by Mishra in view of Dasgupta and combine the method of flaming the seed and using BA in the medium as taught by Gupta. One of ordinary skill in the art would have been motivated to do so given that flaming the seed is a form of scarification to break dormancy. With regard to the BA

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in the medium, Gupta showed that BA was effective in inducing growth (abstract and Table 1). With regard to the potting mix, Gupta is silent to the mixtures but it would have been obvious to use any type of potting mix because most mixes will encourage further development of the plant. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Mishra, Dasgupta and Gupta because Gupta has shown that flaming the seed coat is a way of scarifying the seed coat to encourage quicker growth and that BA was effective in inducing shoot growth. Gupta further taught that shoot growth was always direct without intervening callus formation (p. 151, left col., lines 9-10). Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

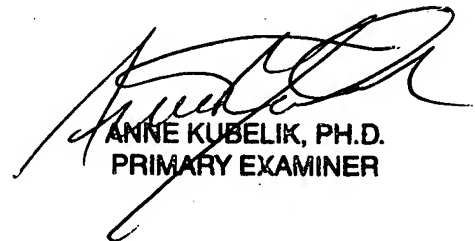
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH.



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER